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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/787,334	02/26/2004	Jason P. Adams	2456.2.14	3985

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EXAMINER
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STULII, VERA

ART UNIT	PAPER NUMBER
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1761

MAIL DATE	DELIVERY MODE
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09/10/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	Application No. 10/787,334	Applicant(s) ADAMS, JASON P.	
	Examiner Vera Stulii	Art Unit 1761	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 28 June 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-46 is/are pending in the application.
- 4a) Of the above claim(s) 23-46 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>05/02/06, 04/25/07, 06/01/04</u> | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Election/Restrictions***

Claims 23-46 withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on June 28, 2007.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is rendered indefinite for the recitation of the phrase "an amount effective to increase nutritional constituents otherwise subject to a deficiency in a user as a normal consequence of consumption". The terms "effective to increase", "subject to a deficiency in a user", and "normal consequence" are relative terms which render the claim indefinite. The metes and bounds of the claimed invention are unclear. Furthermore with regard to "deficiency in user", one is trying to define a composition by situation and subject that is not a part of invention. Furthermore, there appears to be no distinction or way to determine the difference between added amounts of ingredients and those already present. The terms "effective to increase", "subject to a deficiency in a user", and "normal consequence" are not defined by the claim, the specification does

not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

The recitation of a selection from a group of elements in a claim should comply with accepted U.S. Patent practice with regard to the recitation of Markush grouping of claim elements. Phrases using "comprising" are open sets, and should recite elements in the alternative (i.e. "comprising A, B, C or D"), whereas closed sets ("consisting of") should recite elements as "selected from the group consisting of A, B, C and D." See at least claims 1, 3, 5, 12, 13, and 21.

In regard to claims 10 and 11, it is noted that the source of the ingredient whether previously present or later added does not materially effect the composition per se.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**Claims 1-3, 5-6, 10-13, 15-20, 21 are rejected under 35 U.S.C. 102(b) as being anticipated by DAIRY SCIENCE AND TECHNOLOGY HANDBOOK hereinafter DSTH.**

In regard to claim 1, DSTH discloses a liquid beverage directly ingestible by user (milk). DSTH also discloses an active ingredient added to the beverage (p. 4).

In regard to claims 1, 5-6 and 10-11, DSTH discloses adding vitamin A and D to milk products (p.4). In regard to claims 1, 12 and 13, DSTH also discloses chemical excipients that define beverage texture and phase (milkfat globules, casein micelles, globular proteins, lipoprotein particles, water, anti-oxidants) (p. 4). In particular DSTH discloses that milk is "an emulsion of milkfat globules which contain the milk lipids, fat soluble vitamins, and the components of the FGM", and "a colloidal suspension of casein micelles (which contains casein proteins, calcium, phosphate, citrate and water), globular proteins, and lipoprotein particles" (p. 4). Regarding "chemical excipients" recitation, DSTH also discloses that "vitamin E occurs in milk as  $\alpha$ -tocopherol, an important natural anti-oxidant" (p. 29).

In regard to claims 1 and 16-19, DSTH discloses that "[d]airy foods make a significant contribution to the total nutrient intake of the North American population, supplying, for example one-fourth or more individuals protein, calcium, phosphorus, and riboflavin requirements" (p. 4).

In regard to claim 2, DSTH discloses commercially available traditional drink (milk).

In regard to claim 3, DSTH discloses milk.

In regard to claims 15 and 21, DSTH discloses a liquid, suspension, and an emulsion.

**Claims 1-3, 5-7, 10-13, 15-20 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by HANDBOOK OF MILK COMPOSITION hereinafter HMC.**

In regard to claim 1, HMC discloses a liquid beverage directly ingestible by user (milk). In regard to claims 1, 5-7 and 10-11, HMC discloses active ingredients present in the beverage such as vitamins, minerals, electrolytes, amino acid, protein, carbohydrate, fat, etc.). In regard to claims 1 and 16-20, HMC discloses that “[m]ilk and its products contain varying quantities of the B vitamins and ascorbic acid and are excellent dietary source of some” (pp. 2, 464-467, 593, 600, 607, 688-691). HMC discloses that “[a]ll milks contain specific proteins, fat designed to be easily digested, most have lactose, minerals, vitamins and other components which may have important role” (p. 2). HMC discloses that milk contains the following vitamins: thiamine (Vitamin B<sub>1</sub>), riboflavin (Vitamin B<sub>2</sub>), pyridoxine (Vitamin B<sub>6</sub>), cobalmin (Vitamin B<sub>12</sub>), niacin, folic acid biotin, vitamin C (pp. 688-691). HMC discloses that “[t]he monovalent ions, sodium, potassium, and chloride, are among the most prevalent minerals in milk...” (p. 593). HMC discloses that “[t]he divalent ions, calcium, magnesium, citrate, phosphate, and sulphate, are the second most abundant mineral components of human milk” (p. 600, 607). In regard to claims 1, 12 and 13, HMC also discloses chemical excipients that define beverage texture and phase (lipids in emulsified globules, proteins in colloidal dispersion as micelles, etc) (p. 2).

In regard to claim 2, HMC discloses commercially available traditional drink (milk). In regard to claim 3, HMC discloses milk.

In regard to claims 15 and 21, HMC discloses milk which is a liquid, suspension, and an emulsion.

**Claims 1-22 are rejected under 35 U.S.C. 102(b) as being anticipated by van de Hoven et al (EP 0 177 077). HANDBOOK OF MILK COMPOSITION is cited as evidence as discussed above and below.**

In regard to claim 1, van de Hoven et al disclose a composition comprising a liquid beverage directly ingestible by user, an active ingredient added to the beverage, and chemical excipient (Abstract, pp. 4-5). In regard to claim 1, van de Hoven disclose adding active ingredients such as milk and juice (Abstract, pp. 4-5). In regard to claim 1, 12 and 13, van de Hoven et al disclose the following "chemical excipients" pH adjusting agents, flavoring agents, coloring agents, thickening agents, fruit essence, sugars, water or water-containing liquid (Abstract, pp. 2, 4-5).

In regard to claim 2, van de Hoven et al disclose commercially available traditional drinks (milk, juice, alcohol) (Abstract).

In regard to claim 3, van de Hoven et al disclose milk, juice, alcohol (Abstract).

In regard to claim 4 and 14, van de Hoven et al disclose a stable alcoholic beverage containing distilled spirit (alcohol) (Abstract).

In regard to claims 5-11, van de Hoven et al disclose alcoholic beverage based on milk product. As evidenced by HANDBOOK OF MILK COMPOSITION (HMC), milk contains specific proteins, fat designed to be easily digested, minerals, vitamins and other components which may have important role (p. 2). HMC discloses that milk contains the following vitamins: thiamine (Vitamin B<sub>1</sub>), riboflavin (Vitamin B<sub>2</sub>), pyridoxine

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(Vitamin B<sub>6</sub>), cobalmin (Vitamin B<sub>12</sub>), niacin, folic acid biotin, vitamin C (pp. 688-691).

HMC discloses that "[t]he monovalent ions, sodium, potassium, and chloride, are among the most prevalent minerals in milk..." (p. 593). HMC discloses that "[t]he divalent ions, calcium, magnesium, citrate, phosphate, and sulphate, are the second most abundant mineral components of human milk" (p. 600).

In regard to claims 15 and 21-22, van de Hoven et al disclose stable alcoholic beverage containing thickening agents, alcohol, and soured milk. In regard to claim 22, Van de Hoven et al disclose a "yoghurt liqueur" (p.5).

In regard to claims 16-20, van de Hoven et al discloses a stable alcoholic beverage on the basis of soured milk (Abstract). As evidenced by HANDBOOK OF MILK COMPOSITION (HMC), milk contains specific proteins, fat designed to be easily digested, minerals, vitamins and other components which may have important role (p. 2). On page 6 of specification Applicant recites that "[n]utritional deficiency may result from numerous mechanisms and may include, (1) ingestion of foods and beverages that are themselves nutritionally deficient; (2) ingestion of foods and beverages that may deplete nutrient stores in the body; (3) ingestion of foods and beverages that may interfere with the absorption of nutrients in the gastrointestinal system; and (4) co-morbidity with diseases, disorders, or conditions that may deplete nutrient stores in the body. Alcohol, especially chronic, excessive intake of alcoholic beverages, may cause nutritional deficiency through any or all of the above listed mechanisms." Combining alcohol and milk as a nutritional source of proteins, fat, minerals, vitamins and other components, leads to replenishing a deficiency of selected nutrients, inhibiting the



depletion effects of the beverage on nutrients, reversing the depletion effects of the beverage on nutrients, neutralizing depletion effects of the beverage on nutrients, etc. Regarding specific amounts of milk and other nutritional sources, van de Hoven et al disclose 736 kg of whole mil, 264 kg cream, 70 kg saccharose, 10 kg glucose, 264 kg water, and 15 kg of alcohol (pp. 4-5).


### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vera Stulii whose telephone number is (571) 272-3221. The examiner can normally be reached on 7:00 am-3:30 pm, Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Keith Hendricks can be reached on (571) 272-1401. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Vera Stulii

  
**KEITH HENDRICKS**  
**PRIMARY EXAMINER**